DOCKET NO.: CUBE-0002 PATENT
Application No.: 10/664,697 REPLY FILED UNDER EXPEDITED
Office Action Dated: April 19, 2007 PROCEDURE PURSUANT TO
37 CFR § 1.116

REMARKS

I. Status of the Claims

Claims 3-29 are pending in the application. Claims 1, 2, 7, 8, and 14-17 have been cancelled. Claims 5, 18, 19, 24 and 28 have been amended.

Claims have been amended to more clearly define the invention and without prejudice to applicants' rights to pursue the claims in a continuing application. Claim amendments are for the purposes of improved clarity or consistency of claim language unless otherwise noted. No claim amendment should be construed as acquiescence in any ground of rejection. No new matter has been added by this amendment. Support for the amendment to claims can be found throughout the specification and, for example in claims 1 to 29, as originally filed, and for example, in paragraphs [0061], [0069], [0072], [0107], and [0110].

II. Claims Are Patentable Under 35 U.S.C. § 112 first paragraph

Claims 5-13 and 20-24 have been rejected under 35 U.S.C. § 112 first paragraph as allegedly failing to comply with the written description requirement as including new matter not supported by the original disclosure. The Office Action alleged that the specification and claims as originally filed do not provide support for the invention as in claims 5-13 and 20-24. In particular, the Office Action argued that the recitation of an antigenic peptide (R) of any length and containing any type and number of cell-binding ligands, any type and number of amino acids up to 1500 amino acids, anti-inflammatory structures anti-thrombogenic structures, growth factor structures, adhesion barrier structures, and combinations thereof, with the proviso that the MAP has a active functional groups to covalently link the MAP structure to the surface of the substrate (S), is not supported by the specification. The Office Action further argued that the specification is void of any specific guidance wherein variable Z is polylysine up to 500 amino acids in length. Applicants traverse the rejection.

With regard to variable R, applicants have amended claim 5 such that each R when present in the MAP structure comprise a total of up to about 100 amino acids, and wherein R₁ to R₁₆ is GTPGPQGIAGQRGVV (SEQ ID NO: 1). Support for a MAP structure comprising GTPGPQGIAGQRGVV(SEQ ID NO: 1) in a polypeptide up to 100 amino acids can be

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found in the specification, for example, in paragraphs [0100] and [0107], Table 3, Table 4, Table 5; and Table 6.

With regard to variable Z, the application does provide support for Z is lysine, polylysine, ornithine, polyornithine, or β -alanine, wherein the polylysine or polyornithine comprise a total of up to about 500 amino acids. See specification, for example, for example, in paragraphs [0061], [0069], [0072], or [0107]. Applicants provide working examples of MAP structures with lysine, ornithine, or β -alanine as variable Z. With regard to the number of working examples to support an adequate written description, the poly amino acids, polylysine and polyornithine, were well known in the art as of the filing date of the application. What is well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005).

Applicants respectfully request that the rejection of claims 5-13 and 20-24 under 35 U.S.C. § 112 first paragraph be withdrawn.

III. Claims Are Patentable Under 35 U.S.C. § 103(a)

Claims 1-29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nomizu et al. in view of Tam. Applicants traverse the rejection.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or to combine the reference teachings so as to arrive at the claimed invention and there must be a reasonable expectation of success for achieving the claimed invention as a whole. See *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Here, a proper *prima facie* case of obviousness has not been set forth.

Claim 5, as amended, is directed to a composition of matter for the active structure MAP-S wherein MAP is an organic molecule which is covalently bound to a substrate S, in part, and wherein the organic structure MAP is selected from(R)_{n+1}-(Z)_n-X, wherein Z is independently selected from the group consisting of lysine, polylysine, β -alanine, ornithine, or polyornithine, and R_1 to R_{16} are GTPGPQGIAGQRGVV (SEQ ID NO: 1) up to about 100 amino acids.

The Office Action has not established a *prima facie* case of obviousness. Neither the Nomizu et al. reference nor the Tam reference teaches or suggests applicants' claimed

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invention, a composition of matter as in claims 3 to 19 for the active structure MAP-S wherein Z is independently selected from the group consisting of lysine, polylysine, βalanine, ornithine, or polyornithine, and R₁ to R₁₆ are GTPGPQGIAGQRGVV (SEQ ID NO: 1) up to about 100 amino acids. Furthermore, the combination of references does not teach or suggest the claimed pharmaceutical composition of claims 20-21 or the claimed implant of claims 22 to 29 comprising the active structure MAP-S. The Office Action cited the Nomizu et al. reference which refers to a Tam reference to teach multimeric form of the active laminin peptide, YIGSR, but the reference does not teach attachment to a substrate. The Office Action further cited the Ruben et al. reference to refer to MAP attached to a nonimmunogenic lysine core and attached to a polyethylene glycol-polystyrene (PEG-PS) support. The Ruben et al. reference does not cure the deficiency of the primary reference. The combination of references does not teach or suggest applicants' claimed invention. The combination of references does not teach or suggest that the claimed R groups GTPGPQGIAGQRGVV (SEQ ID NO: 1) can form a MAP structure or a MAP-S structure. Claims 5-13, and 22-24 patentably define over the cited prior art. Applicants therefore request that the rejection of claims 5-13, and 22-24 under 35 U.S.C. § 103(a) be withdrawn.

VI. Conclusion

In view of the foregoing, claims 3-29 of the application are now in condition for allowance. The prompt issuance of a formal Notice of Allowance is therefore requested.

If the examiner believes a telephone conference would expedite allowance of this application, please telephone the undersigned at 206-332-1380.

Date: October 19, 2007

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